UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte LAURA E. NIKLASON, ANDY MCKEE, and CECIL BOREL

Appeal 2007-4159
Application 10/074,250
Technology Center 1600

Decided: October 18, 2007

Before DONALD E. ADAMS, ERIC GRIMES, and LORA M. GREEN, *Administrative Patent Judges.*

GREEN, *Administrative Patent Judge.*

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 1, 10, and 11. We have jurisdiction under 35 U.S.C. § 6(b). Claim 1 is representative of the claims on appeal, and reads as follows:

1. A method of treating or inhibiting progression of cerebral vasospasm that follows subarachnoid hemorrhage (SAH) comprising administering to a patient in need of such treatment or inhibition an amount of an agent that inhibits vascular cell proliferation sufficient to effect said treatment or inhibition.

Claims 1, 10, and 11 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Black (U.S. Patent No. 5,527,778, issued June 18, 1996).

According to the Examiner,

> Black discloses that well-known neuropharmaceutical agents such as chemotherapeutic agents, in particular, methotrexate (see col.4 line 57 to col.5 line 10) to be administered to a patient are useful in methods of treating abnormal brain tissue including subarachnoid hemorrhage, head injury (head trauma) and cerebral ischemia, and opening abnormal brain tissue capillaries in a patient, i.e., a mammal (see abstract, col.4 lines 1-9).

(Answer 3.)

The burden is on the Examiner to set forth a prima facie case of unpatentability. *See In re Glaug*, 283 F.3d 1335, 1338, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002). In order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. *See In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). In general, a limitation is inherent if it is the "natural result flowing from" the explicit disclosure of the prior art. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1379, 67 USPQ2d 1664, 1669 (Fed. Cir. 2003). "Inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." *MEHL/Biophile Int'l. Corp. v. Milgraum*, 192 F.3d 1362, 1365, 52 USPQ2d

1303, 1305 (Fed. Cir. 1999)(*quoting In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981)).

Appellants argue that nothing in Black teaches administering a chemotherapeutic agent, such as methotrexate to treat SAH (Br. 17). We agree, and the rejection is reversed.

According to the Examiner, Black teaches a method of treating SAH. The portion of Black relating to the treatment of SAH is reproduced below.

> The present invention is a method for selectively opening abnormal brain tissue capillaries of a mammal in order to allow selective passage of both low and high molecular weight neuropharmaceutical agents into the abnormal brain tissues. The present invention is applicable to treating brain tumors, abnormal tissues resulting from multiple sclerosis, ischemia and cerebral abscess. The invention is also applicable to brain tissue which is inflamed, infected or degenerated due to any number of different diseases. Examples of specific types of abnormal brain tissue include gliomas, metastatic brain tumors, head injury, meningitis, brain abscess, multiple sclerosis, subarachnoid hemorrhage.

Black, col. 3, l. 65-col. 4, l. 9.

Thus, Black contemplates treating a wide variety of conditions. With respect to the neuropharmaceutical agents that may be used, Black teaches:

> Any of the well known neuropharmaceutical agents may be administered in accordance with the present invention. Low molecular weight (100-20,000) as well as high molecular weight (about 20,000 to 70,000) neuropharmaceutical agents may be used. In addition to neuropharmaceutical agents, diagnostic agents may be used including imaging or contrast agents. . . . Exemplary neuropharmaceutical agents include antibiotics, adrenergic agents, anticonvulsants, nucleotide analogs, chemotherapeutic agents, anti-trauma agents and other classes of agents used to treat or prevent neurological disorders. Specific neuropharmaceutical agents which can be administered

> into abnormal brain tissue in accordance with the present invention include cisplatin, carboplatin, tumor necrosis factor-α (TNF-α), methotrexate, 5-FU, amphotericin, immunotoxins, boron compounds, monoclonal antibodies and cytokines, such as interferons, interleukins, transforming growth factors, oligonucleotides.

Black, col. 4, l. 57-col. 5, l. 10

Black's focus, however, is on "increas[ing] the permeability of abnormal brain tissue capillaries" by infusing bradykinin or a bradykinin analog into the carotid artery (*id.* at col. 1, l. 65 to col. 2, l. 2). As noted by Appellants, "Black in no way teaches or . . . suggest[s] that any or all of these neuropharmaceutical agents could be used to treat any or all of the abnormal tissues referenced above." (Br. 17.) There is nothing in Black connecting the use of methotrexate to SAH.

In fact, in Example 2 (col. 8), Black assays the permeability of glial tumors in rats to methotrexate. Thus, Black suggests the treatment of brain tumors with methotrexate, but not SAH. The Examiner has not provided any evidence correlating SAH with tumors of the brain. While it may be possible that a patient diagnosed with a brain tumor may also have an SAH, as noted above, inherency may not be established by probabilities or possibilities. In other words, the Examiner has not established that the population of patients with cancer overlap with patients with SAH so as to establish that one is treating a brain tumor, one is inherently treating the SAH.

REVERSED

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